GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:5653
ANSWERED ON:07.04.2017
Control on Pharma Companies
Jadhav Shri Prataprao Ganpatrao;Vasava Shri Mansukhbhai Dhanjibhai

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has any control over the pharmaceutical companies in the country;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the manner in which the Government controls the manufacturing of life saving drugs so that the poor and needy are not deprived of these medicines;

(d) the measures taken by the Government in this regard; and

(e) the details of outcome of the measures taken?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a) & (b): The manufacturing, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take action against violation of any provision of the Act and Rules. Further, the pharmaceuticals companies that manufacture drugs are required to comply with Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and Good Storage and Distribution Practices (GSP) as per the provision of the said Rules.

(c) to (e): The Ministry of Health & Family Welfare had brought out a new National List of Essential Medicines in 2015 and based on the same, the Department of Pharmaceuticals has revised the Schedule to Drugs (Prices Control) Order, 2013 (DPCO). The National Pharmaceuticals Pricing Authority (NPPA) under the Department of Pharmaceuticals regulates the prices of medicines sold in the country under the DPCO.

In order to examine the quality of drugs, samples of drugs are picked up by both the officers of Central Drugs Standard Control Organisation (CDSCO) and State Drugs Control Department regularly. Further, a nation-wide survey (2014-16) has also been conducted in which 47012 samples were tested and analysed from across the country. The percentage of drugs not conforming to the prescribed standards (Not of Standard Quality) has been found to be 3.16% and that of spurious drugs 0.0245%. The prevalence of such drugs, as such, is very low.
The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.